Bayer

Memorandum

Pharmaceutical Business Group

From Craig Simpson

Date 25 February 1992

To Klaus Behrendt

Ref CDS/ER/252

cc: Neil Edwards
Roger Wheywell

CUTTER PRODUCTS - LICENSING STATUS

Thank you for your memo of 24 February 1992 requesting information on the current status of Cutter products in the UK.

1. Gamimune N (5%)

Currently licensed for the following indications:

a) Replacement therapy for congenital agammaglobulinaemia and hypogammaglobulinaemia.

b) Treatment of idiopathic thrombocytopenic purpura.

c) Prevention of infection in patients undergoing bone marrow transplantation.

Note: Although it does not appear on the data sheet, we also have approval for recommending the product for home therapy in suitable patients.

We currently market 10ml, 50ml, 100ml bottles and a 250ml size is registered and will be launched in April/May 1992.

The only milestoned extension is to include the treatment of patients with chronic lymphocytic leukaemia/multiple myeloma (submission M6 QII 1994, M7 QI 1995).

A dossier is also being constructed by Cutter for a 10% concentration although there are no plans for a UK submission at present.

2. Factor VIII products

We currently hold a product licence for the dry heat-treated product, Koate HT. This was withdrawn from the market a couple of years ago for two reasons, namely, the availability of safer products and the fact that it is no longer manufactured by Cutter. The licence will be allowed to lapse.

Owing to inadequate resources from Cutter, the additional work required to register the next generation wet heat-treated product, Koate HS, was not performed and our licence application was withdrawn.

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All effort has since been put into Cutter's current product, Koate HP, a solvent detergent-treated product. A submission is planned for QII 1992 depending upon priorities. Although there are no current plans to market this in the UK, we are progressing with the dossier in order to support activities elsewhere in Europe (see 5 below).

3. Prolastin

The proposals for licensing this product were reviewed several years ago and it was concluded that in order to obtain a product licence, evidence of efficacy in congenital alpha$_1$ proteinase inhibitor deficiency syndrome would be needed. Currently these data are not available. We have no plans to submit a licence application for this product.

4. Plasbumin 5%, 20%, 25% (Normal Human Albumin)

We currently hold product licences for the above three strengths of albumin solution for the following indications:

a) Treatment of hypovolaemic shock and burns.

b) Treatment of hypoproteinaemia (20% and 25% only).

These products have not been launched in the UK.

5. Re-licensing requirements

Owing to the implementation of several EC (Extension) Directives, we will be re-registering Gamimune N and Plasbumin during 1992, i.e. in a similar way to the allergen products, as previously discussed. The deadline for our submissions is April 1992.

Because of resource problems, both at Cutter in the US and to a lesser extent locally, we have had to prioritise our efforts. Naturally, as it is the only product currently marketed, maximum effort is being put into the application for Gamimune N. Plasbumin is of a lower priority and it might be worth investigating whether or not re-licensing in the UK is actually worthwhile. I would appreciate your comments on this.

Regards.

GRO-C

Craig Simpson